



ATTORNEY DOCKET NO. 2003080-0142(SK-893-B-US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Danishefsky, *et al.* Examiner: TBA
Serial No.: 10/728,041 Art Unit: 1642
Filing Date: December 3, 2003
Title: CLUSTERED MULTI-ANTIGENIC CARBOHYDRATE CONSTRUCTS,
METHODS FOR THEIR PREPARATION, AND USES THEREOF

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313

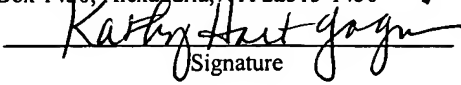
Sir:

REQUEST FOR CORRECTION OF FILING RECEIPT

Applicant respectfully requests correction of the following errors in the Filing Receipt mailed by the USPTO on March 18, 2004, for the above-referenced case:

1. Please correct the Filing Receipt to indicate that the present application claims priority to PCT/US03/22657, filed July 18, 2003, the entire contents of which are incorporated within the present application.

A copy of the Filing Receipt with the correction noted thereon is enclosed as Exhibit A. Enclosed as Exhibit B are a copy of Page 1 of the Application, as filed, and a copy of the Transmittal, evidencing that the priority claim was made at the time of filing. Also enclosed as Exhibit B is a copy of the stamped, returned postcard. Applicant respectfully requests that a corrected filing receipt be issued as soon as possible.

Certificate of Mailing	
I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
Date <u>May 5, 2004</u>	 Signature
Kathy Hart Gagnon Typed or Printed Name of person signing certificate	

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,



Date: May 4, 2004

Nadège M. Lagneau, Ph.D.
Reg. No. 51,908

PATENT GROUP
CHOATE, HALL & STEWART
Exchange Place
53 State Street
Boston, MA 02109
Telephone: 617-248-5000
Facsimile: 617-248-4000



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Commissioner of Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

TRANSMITTAL

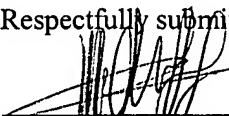
Enclosed please find the following documents regarding the above-referenced matter:

- 1) Request for Correction of Filing Receipt (2 pp.);
- 2) Copy of Filing Receipt mailed by USPTO on March 18, 2004, with change noted thereon (Exhibit A) (2 pp.);
- 3) Copy of Page 1 of Patent Application, as filed, with copy of the Transmittal and the stamped, return postcard (Exhibit B) (7 pp.), and
- 4) Return postcard.

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,

Date: May 4, 2004

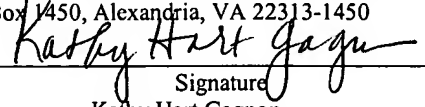

Nadège M. Lagneau, Ph.D.
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Certificate of Mailing

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May 5, 2004
Date


Signature
Kathy Hart Gagnon

Typed or Printed Name of person signing certificate



EXHIBIT A

COPY

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/728,041	12/03/2003	1642	1277	2003080-0142 (SK-893-B-US	35	58	2

CONFIRMATION NO. 4230

FILING RECEIPT



OC000000012134694

ATTN: Nadege M. Lagneau, Ph.D.
 PATENT GROUP
 Choate, Hall & Stewart
 53 State Street, Exchange Place
 Boston, MA 02109

Date Mailed: 03/18/2004

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Samuel J. Danishefsky, Englewood, NJ;
 Stacy J. Keding, New York, NY;

Domestic Priority data as claimed by applicant

This application is a CIP of 10/209,618 07/31/2002
 which is a CIP of 09/641,742 08/18/2000
 which claims benefit of 60/150,088 08/20/1999

Foreign Applications

PCT/US03/22657 07/18/2003

If Required, Foreign Filing License Granted: 03/15/2004

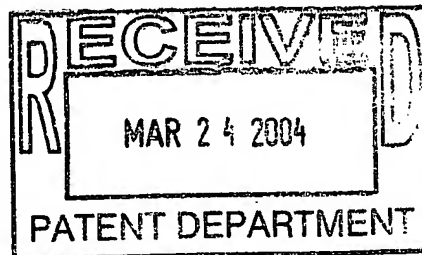
Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title



Clustered multi-antigenic carbohydrate constructs, methods for their preparation, and uses thereof

Preliminary Class

514

**LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

**CLUSTERED MULTI-ANTIGENIC CARBOHYDRATE CONSTRUCTS, METHODS
FOR THEIR PREPARATION, AND USES THEREOF****PRIORITY INFORMATION**

[0001] This application is a continuation-in-part of co-pending patent application No.: 10/209,618 filed July 31, 2002; which is a continuation-in-part of U.S. patent application No.: 09/641,742 filed August 18, 2000, which claims priority under § 119(e) of the United States Code to provisional application 60/150,088, filed August 20, 1999, entitled "Synthesis and Bioconjugation of the n-Pentenyl Glycoside of the Tumor-Associated Antigen Fucosyl GM1". In addition, the present application claims priority to International Application PCT/US03/22657, filed July 18, 2003. Each of the above applications is hereby incorporated by reference in its entirety.

GOVERNMENT SUPPORT

[0002] The present invention was supported by the National Institutes of Health Grant Numbers: AI16943, AI51883 and CA28824. Therefore, the government has certain rights in the present invention.

BACKGROUND OF THE INVENTION

[0003] The improvement of existing therapeutics and the development of novel therapeutics to treat and/or prolong survival of cancer patients has been the subject of continuing research in the scientific community. Although certain of these efforts have been directed to "traditional" chemotherapeutics (*e.g.*, Paclitaxel and other small molecule and/or natural product based therapies) that act by killing malignant cancer cells, it has also been a long-standing goal (Lanzavechis, *Science*, 260, 937-944; Pardoll *et al.*, *Curr. Opin. Immunol.* 1993, 5, 719-725; Livingston *et al.*, *Curr. Opin. Immunol.* 1992, 4, 2; Dranoff *et al.*, *Proc. Natl. Acad. Sci. USA* 1993, 90, 3539; M.H. Taoet *et al.*, *Nature*, 1993, 362, 755; T. Boon, *Int. J. Cancer* 1993, 54, 177) to develop an anti-cancer vaccine that will induce an anticancer immune response. Although cancer vaccines have thus far been perceived as a mode of treatment subsequent to the detection of the disease (for example, by providing an enhanced immunological response), it would be most desirable to develop a selective vaccine that would be able to provide enhanced protection against tumor recurrence and metastasis, for example when the tumor burden has been addressed through surgery, radiation or other chemotherapeutic treatment.



CHOATE, HALL & STEWART

A PARTNERSHIP INCLUDING PROFESSIONAL CORPORATIONS

EXCHANGE PLACE

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BOSTON, MASSACHUSETTS 02109-2804

TELEPHONE (617) 248-5000 • FAX (617) 248-4000

WWW.CHOATE.COM

COPY

MAIL STOP PATENT APPLICATION
COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

Express Mail No.: EV 170393602 US

Attorney Docket No.: 2003080-0142

(SK-893-B-US)


Date Filed: December 3, 2003

CERTIFICATE OF EXPRESS MAILING

"Express Mail" mailing label number EV 170393602 US

Date of Deposit: December 3, 2003

I hereby certify that this correspondence is being deposited with the United States Postal Service as "*Express Mail Post Office to Address*" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450


KATHY HART GAGNON

UTILITY PATENT APPLICATION TRANSMITTAL

(for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Dear Sir:

Please find enclosed a patent application and papers as follows for:

Inventor(s):

Given Name (first and middle)	Family Name or Surname	Residence
Samuel J.	DANISHEFSKY	22 Brayton Street Englewood, NJ 07631
Stacy J.	KEDING	1233 York Avenue, Apt. 13G New York, NY 10021

**Title of the Invention: CLUSTERED MULTI-ANTIGENIC CARBOHYDRATE CONSTRUCTS,
METHODS FOR THEIR PREPARATION, AND USES THEREOF**

A) APPLICATION ELEMENTS:

1) **Fee Transmittal Form** (original and duplicate submitted for fee processing)

2) X **Applicant Claims Small Entity Status** (see 37 CFR §1.27)

a) **Statement Verifying Small Entity Status**

3) X **Specification**

TOTAL PAGES: 183

(including 166 pp. description, 16 pp. claims, 1 pg. abstract

- Descriptive Title of the Invention
- Priority Information
- Government Support
- Background of the Invention
- Summary of the Invention
- Definitions
- Brief Description of the Drawing
- Detailed Description of Certain Preferred Embodiments of the Invention
- Equivalents
- Exemplification
- Claim(s) (16 pp.)
- Abstract of the Invention (1 pg.).

4) X **Drawing(s)** (35 U.S.C. § 113)

TOTAL SHEETS: 35

a) **Formal Drawings** (if checked)

5) **Oath or Declaration**

TOTAL PAGES:

a) **Newly Executed** (original)

b) **Copy from a prior application (37 C.F.R. § 1.63(d))-for
continuation/divisional application**

c) **Unexecuted**

6) **Application Data Sheet.** See 37 CFR 1.76.

7) **CD-ROM or CD-R in duplicate, large table or Computer Program
(Appendix)**

8) **Nucleotide and/or Amino Acid Sequence Submission** (if applicable, all are
necessary)

a) **Computer Readable Form (CRF)**

- b) ☐ Specification Sequence Listing on:
- i) ☐ CD-ROM or CR-R (2 copies); or
- ii) ☐ Paper (☐ pages)
- c) ☐ Statements verifying identity of above copies
- d) ☐ Amendment Introducing Sequence Listing

B) ACCOMPANYING APPLICATION PARTS:

- 9) ☐ **Assignment Papers**
- 10) ☐ **37 C.F.R. § 3.73(b) Statement**
- 11) ☐ **Power of Attorney;**
- 12) ☐ **English Translation Document (if applicable)**
- 13) ☐ **Information Disclosure Statement (IDS)/PTO-1449**
- 14) ☐ **Statement Under 37 C.F.R. §§ 1.56, 1.97 and 1.98**
- 15) ☐ **Copies of IDS Citations**
- 16) ☒ **Return Receipt Postcard (MPEP 503) (specifically itemized)**
- 17) ☐ **Certified Copy of Priority Document(s) (if foreign priority is claimed)**
- 18) ☒ **OTHER: (if applicable, specified below)**

(a) Appendix A – Cross-Linking (30 pp.)

C) FOR CONTINUING APPLICATIONS: (the appropriate box is checked, and certain information is provided below and in a preliminary amendment)

☐ CONTINUATION ☐ DIVISIONAL ☒ CONTINUATION-IN-PART (CIP)

OF PRIOR APPLICATION NO:	10/209,618
FILED:	July 31, 2002
EXAMINER:	Karen A. Canella
GROUP/ART UNIT:	1642

FOR CONTINUATION OR DIVISIONAL APPLICATIONS ONLY: THE ENTIRE DISCLOSURE OF THE PRIOR APPLICATION, FROM WHICH AN OATH OR DECLARATION IS SUPPLIED AS DETAILED ABOVE, IS CONSIDERED A PART OF THE DISCLOSURE OF THE ACCOMPANYING CONTINUATION OR DIVISIONAL APPLICATION AND IS HEREBY INCORPORATED BY REFERENCE.

D.) PRIORITY CLAIM(S):

This application claims the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America listed below:

10/209,618 09/641,742	July 31, 2002 August 18, 2000	Pending Pending
Application Number	Filing Date	Status

PCT Applications designating the United States:

PCT/US03/22657	July 18, 2003	Pending
Application Number	Filing Date	Status

This application claims the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

Provisional Application(s):

60/150,088	August 20, 1999	Expired
Application Number	Filing Date	Status

E) METHOD OF PAYMENT OF FILING FEES FOR THIS APPLICATION:

X Applicant claims small entity status 37 CFR §1.27

X A check in the amount of \$ 1,277.00

X The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number 03-1721.

Basic Filing Fee (<u>SMALL</u> Entity)	\$385.00
Additional Fees:	
Total Number of Claims in excess of 20: (103 - 20) = <u>83</u> x \$ <u>9</u>	\$747.00
Number of Independent Claims in excess of 3: (0) x \$ <u>43</u>	\$0.00
Multiple Dependent Claims – YES	<u>\$145.00</u>
Total Filing Fee:	\$1,277.00

F) CORRESPONDENCE ADDRESS:

PATENT GROUP
Choate, Hall & Stewart
53 State Street
Exchange Place
Boston, MA 02109
ATTN: Nadège M. Lagneau, Ph.D.
Telephone: (617) 248-5000
Facsimile: (617) 248-4000

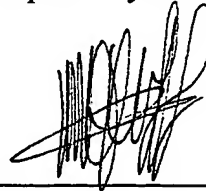
G) GOVERNMENT SUPPORT:

THE INVENTION WAS MADE BY AN AGENCY OF THE UNITED STATES GOVERNMENT OR UNDER A CONTRACT WITH AN AGENCY OF THE UNITED STATES GOVERNMENT:

 NO

 X YES, THE NAME OF THE U.S. GOVERNMENT AGENCY AND THE GOVERNMENT CONTRACT NUMBER ARE : NATIONAL INSTITUTES OF HEALTH GRANT NUMBERS AI16943, AI51883 AND CA28824.

Respectfully Submitted,



Nadège M. Lagneau, Ph.D.
Reg. No. 51,908

Dated: December 3, 2003

PATENT GROUP
CHOATE, HALL & STEWART
53 State Street
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Boston, MA 02109
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Facsimile: (617) 248-4000

Dated: December 3, 2003

Express Mail: EV 170393602 US

BHJ/NML/NH

22390 U.S. PTO
10/728041



120303

The Patent and Trademark Office stamping sets forth filing and receipt date (or both the receipt date and the Serial Number) of a US Utility Continuation-in-Part Patent Application identified as follows:

Applicant: Danishefsky *et al.* Examiner: NYA
Serial No.: NYA Art Unit: NYA
Filed: December 3, 2003
For: CLUSTERED MULTI-ANTIGENIC CARBOHYDRATE
CONSTRUCTS, METHODS FOR THEIR PREPARATION,
AND USES THEREOF

COPY

1. Specification (183 pages), including 166 pages of description,
16 pages of claims; 1 sheet of abstract;
2. Appendix A -- Cross-Linking (30 pages);
3. Informal Drawings (35 pages);
4. Application Transmittal (5 pages);
5. Check in the amount of \$1,277.00 for filing fee; and
6. This return postcard.

Using: Small Entity Status

BHJ/NML

Case No. 2003080-0142 (SK-893-B-US)

